

**The Development of a Diabetes Group Visit Program  
In a University-Based, Primary Care Clinic**

By

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## ABSTRACT

**Objectives:** This study was conducted to determine the feasibility of a group visit program for diabetes education and management led by a primary care provider in a primary care clinic setting.

**Intervention Design:** A review of the literature about group visits for many diseases including diabetes is reported. Using this information, we designed a diabetes education program using a group visit model. The curriculum was based on the National Standards for Diabetes Self-management Education and used the theory of stages of change and principles of active, adult learning.

**Methods:** 32 subjects with Type II diabetes were recruited to enroll in the program over the course of eight months. Outcome measures included HgbA1c, body mass index, blood pressure, quality of life, and self-efficacy. Changes were measured at baseline, eight weeks, and six months.

**Results:** Clinical outcomes demonstrated trends towards improvement with a 0.16% drop in HgbA1c at six months. Attitudes about diabetes and self-efficacy improved immediately after the sessions but returned to baseline at 6 months. Quality of life showed minimal improvement.

**Conclusions:** A group visit program for diabetes education and management led by a primary care provider is feasible. Key implementation issues included limited patient recruitment and poor attendance rates. Future research is needed to study the development of a group model for continuing management of diabetes in primary care.

## INTRODUCTION

Diabetes is a major contributor to morbidity and mortality in the United States and the world. An estimated 17 million people in the US have diabetes, with nearly 800,000 new cases each year, and diabetes is now the 6<sup>th</sup> leading cause of death in the US.[1] Direct and indirect costs were estimated at \$98 billion in 1997.[1] Chronic complications of diabetes, including micro-vascular and macro-vascular disease, are known to be leading causes of blindness, renal failure, and non-traumatic amputation in the US. Major advances have been made in the management of diabetes with new oral medications, laser therapy to delay the progression of retinopathy, ace-inhibitors to delay renal disease, and more. Trials have successfully demonstrated the benefits of tight glycemic control in both Type I and Type II diabetes and the benefits of aggressive control of blood pressure in Type II patients.[2, 3]

Despite these advances, our current healthcare system is not optimally treating patients with diabetes. An estimated 5.9 million people have diabetes but do not know it. [1] Many of these patients are not diagnosed until several years into the disease process, when complications have already begun. Equally discouraging is the number of patients who receive inadequate or ineffective treatment for their diabetes.[4] Data from the NHANES III Survey in 1988-1994 found that

18% of patients with diabetes had poor glycemic control with HgbA1c levels greater than 9.5%. [5] The Center for Disease Control and Prevention reports that, based on self-report, only 61% of diabetics have had annual dilated eye exams, 55% reported a foot exam in the last year, and only 18% reported a HgbA1c level measured in the last year. [6]

The reasons for this inadequate management of diabetes involve many factors. One major issue is the nature of the disease. Like many chronic diseases, diabetes management involves lifestyle changes that are very difficult to make. Diabetes requires that the patient live with and manage the disease on a daily basis. Treatment entails self-monitoring of blood glucose, medication adherence, and appropriate medical follow-up for screening and prevention. Behaviors such as over-eating, poor food choices, smoking, and lack of exercise contribute to the development of the disease and its poor control. Recent evidence demonstrated that lifestyle change can be more powerful than medications for the prevention of Type II diabetes. However, to be successful, this intervention required an intensive, multidisciplinary team approach to motivate and maintain behavior change. [7]

These challenging aspects of chronic management for diseases like diabetes bring into question our current health care system and its organization. The present structure evolved in an earlier era when acute illness predominated. One-on-one, brief and isolated office or hospital visits made sense. Today, financial pressures have made those visits

even briefer, often requiring physicians to see their patients for less than 15 minutes. Clearly, this design does not meet the needs of patients with complex chronic diseases like diabetes. Physicians need time to introduce knowledge, teach skills, and motivate behavior change in addition to the medical management that must occur in those 15 minutes.

To address these weaknesses, many have proposed creating new structures and systems for management of diabetes and other chronic diseases. Disease management programs, physician reminder systems, and use of multi-disciplinary teams have all been tried and, in some cases, found to be effective[8]. Others have implemented group visits for patients with diabetes; as education and self-management programs, support groups, and as ongoing management visits. Several successful programs have been implemented in large health care systems, but few programs have been studied on a smaller scale. Primary care physicians, often in smaller clinic settings, care for nearly 75% of patients with Type II diabetes.[9] The development of strategies that improve the quality and efficiency of care in primary care settings is essential.

Therefore, we designed a diabetes education and management program using a group visit model, run by individual primary care providers in an academic family practice clinic. The unique feature of our program is the combination of the smaller clinic setting with a primary care provider-led group. The goal of this study is to assess the feasibility of this type of diabetes education and disease management program in a real-

world clinical setting. This paper will review the literature on diabetes group visits and discuss the design and implementation of our program. Initial pilot study data will be presented from the first six cohorts.

### **REVIEW OF LITERATURE ABOUT GROUP VISITS**

Many researchers and clinicians have proposed group visits for a wide variety of health-related concerns, including diabetes education and management. They argue that group visits offer an appealing efficiency for both providers and health care organizations.[10] The potential ability to provide higher quality care to more patients quickly has its obvious benefits. Physicians may prefer to offer the same counseling information once to many patients instead of giving a shortened version of that same education numerous times. Other practices have developed group visits to meet patient demands for increased access to their physicians and to health information.[11]

Some researchers suggest that group visits can offer more than efficiency, noting that group communication and social support have the potential to motivate and reinforce behavior change. In a 1985 article, Tattersall, et al describe twelve potential "curative factors" of group psychotherapy for patients with diabetes.[12] These factors highlight the potential power of group interaction for education, social support, and motivation that cannot be reproduced by one-on-one interaction between

provider and patient (Table 1). Other literature suggests the importance of social support for health behavior change.[13]

Many disease processes can benefit from using a group visit model. In practice, providers appear to develop group programs to meet three needs: 1) increased efficiency and productivity; 2) increased patient access to appointments; and 3) improved education and access to information. Stanford Health Partners led patient focus groups to identify ways that care could be improved and found that access to appointments and information were consistent needs for all patients.[11] Several small private practices have adopted provider-run groups for common conditions such as obesity, depression, and asthma.[14] Another application of the group model is for annual physicals—called Physicals Shared Medical Appointment.[15] These visits limit the traditional physical exam and, instead, focus on health maintenance, healthy lifestyle counseling, and prevention. Patients have the advantage of increased availability of physical appointment times, longer visits with the physician for counseling, and the opportunity to learn from peers.

Group visits have also been studied for well childcare, emphasizing the education and guidance components of these preventive visits. Parents with children of similar ages can learn from each other and form a peer group for social support. One study demonstrated that well childcare could be equally effective when provided using group visits instead of individual visits.[16, 17] Furthermore, group visits were more efficient for

the providers, while allowing parents more time with the physician.

Prenatal care can be provided with the same group framework, focusing on guidance, information sharing, and support.[18]

Several large randomized controlled studies have been conducted using group visits for the care of the elderly or chronic disease. Wagner and Coleman studied the use of group visits for older patients with a chronic disease in a large HMO and found no change in outcomes or cost, but did find an improvement in satisfaction with care.[19] Another study by Beck et al looked at the use of groups for the elderly and found a decrease in emergency room and specialty visits, but an increase in primary care visits and phone calls. Both patients and physicians experienced improved satisfaction, and the overall cost of care for the group patients was less.[20]

The concept of group visits for diabetes education and, more recently, for disease management is spreading. Group education programs have been done for years, though often without direct evidence of the effectiveness. Diabetic “mini-clinics” have been used in Britain for the past three decades as a way to provide specialized disease management in general practice.[21, 22] More recently in the United States, providers have developed comprehensive diabetes education and management using a group visit model. One family physician from Florida has developed a group visit model for several chronic diseases including diabetes, providing routine medical management, education, and support



at each visit.[23, 24] Another program in Sweden looked at pharmacy-run diabetes “circles” that provided education and social support.[25] A recent systematic review of 72 randomized controlled trials in diabetes self-management training found great diversity among the types of programs offered.[26] Short-term measures such as knowledge, blood glucose testing skills, and self-reported dietary habits improved, but often without improved glycemic control. Important findings include the benefits of patient participation and collaboration, the value of reinforcing interventions, and the effectiveness of group interventions for lifestyle change.

Several randomized controlled trials have examined the role of a group model. Detailed characteristics and findings for each trial are shown in Table 2. A 1988 study from Israel examined the role of small group education sessions as part of routine care compared to individual office visits alone. This early study did not demonstrate knowledge differences between the two groups, but did find reductions in fasting and post-prandial glucose ( $p=0.01$ ) and in HgbA1c at 12 months ( $p\leq 0.05$ ).[27] Anderson studied a patient empowerment program. The goal of six weekly group sessions was “empowerment facilitating a path to personal self care.” Patients who attended the sessions demonstrated increased self-efficacy scores (based on a diabetes attitude survey) and greater improvement in HgbA1c.[28] Ridgeway et al studied a practical education and behavior modification program implemented in a small private internal

medicine clinic. Patients attended monthly group sessions led by an RN or RD in addition to their routine office visits. Subjects in the intervention group had a 2.07% drop in HgbA1c at the end of 12 months compared to 1.08% in the control group ( $p=0.0034$ ).[29] A similar program in Denmark studied the effect of a group program for intensified lifestyle education and found limited change in diet and other targeted behaviors but did find reduction in overall HgbA1c levels ( $p<0.0000001$ ).[30] However, this was a multi-factorial intervention and much of the improvement in glycemic control is likely due to other aspects of the intervention such as medication adjustment and intensive target goals for the intervention group.

On a larger scale, two randomized controlled trials have been implemented in health maintenance organizations. Sadur et al studied the efficacy of a cluster visit for diabetes management.[31] Subjects received care provided by a large multi-disciplinary team with monthly group visits over a 6-month period. HgbA1c levels dropped by 1.3% in the intervention group compared to 0.2% in the control group ( $p<0.0001$ ). Hospital and outpatient utilization were lower in the intervention group as well. Wagner et al studied the use of Chronic Care Clinics for diabetes in a large staff model HMO.[32] Subjects attended half-day clinic sessions every three to six months based on the “mini-clinic” model used in Britain. These sessions included individual visits with each member of a multi-disciplinary team and a group education/peer support meeting. After 24 months, the intervention group received more preventive services,

experienced improved quality of life (measured by the SF-36 questionnaire and bed disability days), but showed no significant improvement in HgbA1c. Intervention subjects had increased primary care visits, but needed fewer emergency room and specialty visits.

One study expressly compared group to individual diabetes education using a consistent, evidence-based curriculum modeled on the National Standards for Diabetes Self-Management Education (DSME). The entire program consisted of four sessions over a six-month period led by a nurse and a dietician. The individual and group programs were equally effective at improving knowledge, behavior, attitudes and quality of life. However, the subjects in the group intervention had a statistically significant greater reduction of HgbA1c compared to the control group (2.5% vs. 1.7%,  $p=0.05$ ).[33]

An innovative study from Italy examined the effectiveness of group visits with structured education for routine diabetes care as an alternative to individual visits with support education. After two years of follow-up, patients in the group visits had stable HgbA1c levels compared to elevated levels in the control group ( $p<0.002$ ).[34]

As with the majority of diabetes education research, there is great diversity in the group programs studied. Group sizes ranged from 4 to 20 patients. Group leaders varied from a single provider to a multi-disciplinary team. Professionals involved included physicians, registered nurses, dieticians, psychologists, certified diabetes educators, social

workers, podiatrists, and pharmacists. Programs have been studied in the United States and internationally; in private clinics, academic centers, and large HMO's; and in both diabetes specialty clinics and primary care clinics. Also significant is the wide range of organization and content for the group visits themselves; some were strictly education programs, while others included a disease management component. Frequency, duration, and session time varied greatly. Despite these differences, many similarities in program design exist. Most applied the theories of active adult learning and social support. Curricular content, when described, followed very similar basic themes as recommended by the National Standards for DSME. Overall, this diverse research presents some promising evidence for the potential role of group visits in diabetes education and disease management.

### **CHARACTERISTICS OF THE INTERVENTION-PROGRAM DESIGN**

Our program was designed based on the knowledge of previous programs found in the literature and based on several key theories of behavior change and adult learning.

1) Transtheoretical model: The stages of change theory was incorporated explicitly into the curriculum—both for developing individualized goals for patients but also as a teaching tool to help patients understand their own patterns of behavior change. We included an explicit explanation of the stages of change within the curriculum and

asked patients to assess their own stages for particular behaviors related to diabetes during group discussions.

2) Social Support: Our goal was to encourage group interaction and support between the group members. Enabling and encouraging group participation and sharing of individual experiences with diabetes helps to create supportive relationships apart from the doctor-patient relationship. Further, we hoped that the group members might find more cultural and lifestyle similarities with each other that would promote learning and motivation not always possible with professionals.

3) Active adult learning: Participants were encouraged to participate, ask questions, and help shape the content of discussions. The overall course design minimized the amount of time spent on didactic teaching and focused more on question and answer sessions as well as hands-on activities and group discussion. Homework was incorporated into the design to keep participants actively involved during the time between sessions.

The group visits were led by one of two primary care providers with special interest in diabetes, one FNP/CDE and one Family Physician. Nursing students or resident physicians observed some of the sessions. Clinic staff (nurses or nursing assistants) provided assistance at the beginning of each session for vital signs. The choice of a program run primarily by a single provider was explicit in order to assess the feasibility

of such a program in a smaller primary care setting where access to a multi-disciplinary staff is less likely to be available.

Overall, the program consisted of four 2.5-3 hour sessions every two weeks for a total of an eight-week program. Following the eight-week program, patients were referred back to their primary care provider for ongoing management of their diabetes. Groups were held in an education room within the UNC Family Practice Center. Sessions were offered both during daytime and evening hours, and spouses or significant others were encouraged to attend.

Each session followed a similar outline. Before the session, the provider would review the chart for lab results or ongoing medical issues to prepare an individualized plan for each patient—arrangements for medication changes, lab tests, or screening exams were made. Vital signs including blood pressure and weight using a bio-impedance scale were measured. Each session started with an introduction including questions from the previous session and goals for the day, followed by an interactive teaching session on the main topic for the day, which often involved review of homework assigned at the previous session. Group members were encouraged to ask questions and participate in discussion. A short break including a healthy snack allowed some time for brief (three to five minutes) individual assessment time to review individual needs or changes. This was followed by a group activity focusing on a hands-on skill such as blood glucose monitoring, foot care, or portion sizes. A final

wrap-up reviewed questions and presented goals and homework assignment for the next session.

Sessions were billed as routine office visits and coded as an established patient, complex office visit (99214) for the first session and an established patient, detailed office visit (99213) for the subsequent sessions. Visits included a component of history, some physical exam and lab assessment, medical decision-making, and extensive counseling justifying these codes.

The curriculum was based on the American Diabetes Association guidelines for DSME core content areas.[35] These ten content areas ensure that the basic knowledge and behavioral skills are covered. They include:

- Describing the diabetes disease process and treatment options
- Incorporating appropriate nutritional management
- Incorporating physical activity into lifestyle
- Utilizing medications (if applicable) for therapeutic effectiveness
- Monitoring blood glucose, urine ketones (when appropriate), and using the results to improve control
- Preventing, detecting, and treating acute complications
- Preventing (through risk reduction behavior), detecting and treating chronic complications
- Goal setting to promote health and problem solving for daily living

- Integrating psychosocial adjustment to daily life
- Promoting preconception care, management during pregnancy, and gestational diabetes management (if applicable).

Our curriculum was designed only for patients with Type II diabetes so issues related to Type I diabetes such as urine ketones and ketoacidosis were not discussed unless questions were raised. Also, given to the age of our population, we did not include standard discussion of pregnancy-related concerns. The content areas were divided among the four sessions beginning with basic knowledge and skills and ending with psychosocial aspects of self-care in the last session.

### ***Session 1: Introduction to Diabetes***

Topics covered included the definition of diabetes, signs and symptoms, and basic treatment methods. Physiology of insulin resistance and basic nutrition information was reviewed. Patients participated in a hands-on activity to learn self-monitoring of blood glucose. Homework included lab tests when appropriate, a three-day food diary, and patients were asked to bring two food labels for discussion to the following session.

### ***Session 2: Living a Healthy Life***

The diabetes food pyramid and meal planning were presented using examples from patients own food diaries. Basic educational material from the ADA was distributed. Some healthy cooking techniques were discussed and examples of resources for healthy recipes provided. Special emphasis was placed on portion sizes using both plastic models



and real food demonstrations. In a hands-on group activity, we practiced label reading and made comparisons of different food choices. Key concepts such as serving size, importance of all carbohydrate not just sugar, and goals for total fat and saturated fat intake were stressed. Exercise and its relationship to blood sugar control was discussed, and homework included a three-day activity diary and pre- and post-exercise blood glucose testing.

### ***Session 3: Living in the Doctor's World: Goals for Treatment***

Exercise diaries were reviewed as well as blood glucose responses to exercise followed by a presentation of the basic categories of medication with links to the pathophysiology of disease. The group was then asked to develop a list of complications caused by diabetes using a drawing of the human body as a visual tool. Once a complete list was generated, fundamental prevention measures such as blood pressure control, eye exams, and cholesterol lowering were reviewed. Patients were given an individualized diabetes report card to follow their required preventive services and to set personal goals for treatment. The hands-on skill session reviewed basic do's and don'ts of foot care and individual foot exams. Homework was assigned to think about the issues related to behavior change. The stages of change model was introduced. Patients were asked to think of one success and one failure that they have had in dealing with diabetes.

#### ***Session 4: Putting It All Together: The Key to Happiness and Health***

This session emphasized the challenges of making lifestyle changes. Discussion of the homework assignment prompted patients to develop a list of helpful and harmful techniques to maintain successful change. Using the stages of change model as a framework, we discussed taking small steps towards success. We discussed the effect of illness on diabetes and reviewed the basic steps to managing sick days as well as danger signs. We then discussed the role of emotional stress and its effect on diabetes and presented some stress management skills. Finally, we addressed the issues of communication with health care personnel and with family and friends. Using case examples, we prompted discussion of several “what if” scenarios such as how to handle the family holiday meal. This final session ended with a diploma ceremony for each participant.

### **METHODS: CHARACTERISTICS OF THE EVALUATION**

#### **Study Design**

This study was a feasibility study designed as a non-randomized, pre- and post-intervention evaluation. The research question was whether a provider-run, diabetes group visit program was feasible in our academic family practice center. Future research will require an experimental design with control subjects to determine true effectiveness.

## **Setting**

The setting was the University of North Carolina Family Practice Center in Chapel Hill, North Carolina, a large primary care clinic with 45,000 patient visits per year with both resident and faculty providers. Patients have diverse backgrounds, including highly educated university personnel, rural farmers, and elderly Medicare patients.

## **Recruitment of Subjects**

Subjects were recruited from continuity patients at the UNC Family Practice Center identified as having Type II Diabetes by ICD-9 diagnosis codes. Letters were sent to over 740 patients with diabetes announcing the new program and asking interested patients to call the study coordinator or to speak with their physician. Fliers were sent to each of the physicians in the practice; announcements were made at clinic meetings to make providers and staff aware of the program; and informational posters were placed in each exam room. Patients could be referred to the program either by their physician or at their own request.

Once a patient was referred to the program, the research assistant contacted patients by telephone to explain the program, review the study components, and obtain a basic verbal consent for the program. A telephone script was used for these phone calls. Basic exclusion criteria were reviewed with each patient. These included patients under age 18, pregnancy or planned pregnancy within the next year, inability to

participate in all four sessions, and plans to change providers within the next 12 months.

Specific cost information was explained to each potential participant including relevant co-payments and other charges. The overall charge for the program was \$319 plus the cost of any indicated lab tests. All of the testing done for the study and the visits themselves were felt to be consistent with routine diabetic care and, therefore, patients and their insurance were billed.

Following the telephone interview, patients either declined to enroll in the program or were scheduled for the next group session. Figure 1 displays the number of patients initially recruited, the number enrolled, and the number who attended. Primary reasons for declining the program included schedule conflicts, cost and lack of insurance, and new health-related concerns with higher priority. The patients identified by this type of recruitment are self-selected or physician-selected and are likely to be more motivated than the average diabetic population.

Written informed consent was obtained at the beginning of the first session. The Institutional Review Board for the UNC School of Medicine approved our study.

### **Data and Data Collection**

Baseline demographic and clinical information was obtained for all patients who enrolled in the group visit program using review of the electronic medical record. Specific clinical data such as duration of

diabetes, medications, co-morbid conditions, presence of complications, and previous lab test results were recorded. Lab data were considered baseline if tests had been done within the standard recommendations for routine diabetes care. For example, HgbA1c results were considered baseline if drawn less than three months before the onset of the first group session whereas cholesterol and urinary microalbumin results were baseline if done within the last 12 months. If subjects did not have documentation of baseline lab results, arrangements were made to have them done within the first two weeks of the group visit program.

Outcome measures were divided into five basic categories: 1) Clinical measures; 2) Attitudes and self-efficacy measures; 3) Quality of life measures; 4) Quality of care; and 5) Utilization measures.

### **Clinical Outcomes**

HgbA1c was measured using the DCA 2000 Analyzer by Bayer Diagnostics, with a normal range 4.8-6.0%. These values were obtained from electronic chart review at the onset of the group program and at six months after the intervention when possible. Long-term follow-up will also include 12-month measures. Subjects were to obtain these tests as part of the routine management of their diabetes. However, due to low compliance with these routine recommendation discovered during the process of this research, reminder messages were sent to patients and their primary care providers to ensure this and other clinical testing was done.

Total cholesterol (and, when possible, calculated LDL cholesterol) was followed at baseline and 12 months. These were measured using materials provided by Roche Diagnostics. The normal range for total cholesterol is 1-199 mg/dl and 1-129 mg/dl for LDL.

Weight and Body Mass Index were measured using a bio-impedance scale at each of the group sessions. Follow-up weight was recorded from electronic chart review from subsequent patient visits at six-month and 12-month endpoints. Visits within four weeks of the time point (before or after) were considered adequate for each follow-up measure. These were typically obtained with a basic balance scale and BMI was calculated using known height.

Systolic and Diastolic Blood Pressures were obtained at the onset of each group sessions by clinical support staff using the traditional auscultation technique. Follow-up blood pressure measures documented at routine clinic visits at six-month and 12-month points were obtained from electronic chart review. Visits within four weeks of the time point (before or after) were considered adequate for each follow-up measure.

### **Attitude and Self-Efficacy**

Attitudes and self-efficacy were measured using a previously designed and validated survey called the *Diabetes Empowerment Scale*, developed by Anderson et al at the University of Michigan.[36] Permission was obtained from the University of Michigan Diabetes Research and Training Center for use of this instrument. It is a 28-item Likert-type

questionnaire that addresses attitudes about diabetes on a 1 to 5 scale. An overall score is measured as well as three subscales: Managing the Psychosocial Aspects of Diabetes, Assessing Dissatisfaction and Readiness to Change, and Setting and Achieving Diabetes Goals. A higher score indicates better attitudes about diabetes and increased self-efficacy.

Subjects completed questionnaires at the onset of the program, on completion of the four session, at six-months, and at 12-months. Both six-month and 12-month questionnaires were mailed to subjects' homes with return envelopes and postage provided along with a reminder phone call.

### **Quality of Life**

The SF-12® survey, a shortened version of the SF-36® survey that has been validated in many disease processes, was used to assess health-related quality of life.[37, 38] This survey has subscales for both physical (PCS) and mental (MCS) health components. Permission was obtained for use from Quality Metric Incorporated. An online scoring service was used to analyze the data using the weighted analysis designed and tested for this survey. As a reference, the mean score found in a general U.S. population was 50.12 (SD 9.45) for the PCS and 50.04 (SD 9.59) for the MCS. Higher scores indicate better quality of life.[39]

Subjects completed the SF-12® surveys at onset of the group sessions, at the end of the last session, and at 6-month and 12-month

follow-up points. Surveys were mailed along with the Empowerment questionnaires.

### **Future Outcome Measures**

Both quality of care and health care utilization are important long-term measures of any clinical diabetes program. These measures will be examined after 12 months of follow-up to look for any effect of enrollment in the program.

Quality of care measures will include use of recommended medication such as aspirin and ace-inhibitors and rates of annual eye exams and influenza immunizations. These measures will be examined at baseline through medical chart review and direct history from the patient. Final comparison of these measures will be looked at after 12 months to see if rates change over a 12-month period.

Healthcare utilization will be tracked using an administrative database for the entire university health care system. Office visits, emergency room visits, and hospitalizations within the UNC system in the 12 months prior to the program will be compared to the 12 months after the intervention.

### **Analysis**

Descriptive statistics were obtained to determine the baseline characteristics of the enrolled subjects for important demographic and clinical areas. Pre-intervention and post-intervention outcomes measure means were calculated and compared. Values are presented as means



or percentages where appropriate. This study's primary goal was to assess the feasibility of this group visit program in our setting. Therefore, it was not designed to have adequate power to detect differences in any of the outcomes areas. Measures of statistical significance would be misleading and are not reported.

### **IMPLEMENTATION OF THE PROJECT**

The most challenging aspect of implementation was contacting and scheduling patients. A part-time research assistant working 8-10 hours per week spent much of her time making repeated phone calls in order to reach patients on the telephone. Even though they made inquiries about the program, we were not able to contact 30% of interested patients, primarily due to lack of access to work phone numbers and incorrect phone numbers. Of those patients who agreed to enroll in the program, a significant number of patients did not show up for any of the classes (15 out of 47). One entire group had to be re-scheduled to start the following week as only one of the six subjects showed up for the first session. More frequent phone call reminders, contacts made during evening hours, and a better system of mailing notices to patients may have helped attendance rates. Involvement of the primary care provider in this contact process may help to encourage better enrollment and attendance rates.

Incorporating a new clinical program into an already busy clinic system was another challenge. All plans were reviewed with clinic

managers, nursing, and lab personnel to anticipate any potential problems. We had to carefully choose the times and days of the week for the session so that the arrival time of the group patients would not overwhelm clinic staff. Informing and working with front desk staff in the clinic made processing referrals, answering patient questions, and overall scheduling of patients somewhat easier.

Overall attendance was fair. Two subjects attended only the first session while 11 out of 32 subjects attended all four sessions. On average, subjects attended three sessions. Reasons for missing a session included transportation problems, family or personal illness, or failing to remember. Subjects were not called between sessions, but they did receive a computerized reminder card before each meeting.

The lower rates of enrollment and attendance than anticipated weakened the cost-effectiveness of the program. Overall, the six cohorts required 24 half-day sessions of provider time. The total amount billed for the entire program was \$8983, approximately \$375 per session. This is about half of what each provider would typically bill in a continuity clinic half-day session. Some of this reduced billing can be justified by the limited use of clinic resources such as nursing needs and clinic rooms, but to be cost-neutral for our clinic, group size needs to reach eight or nine patients.

Provider time involved in the sessions improved with experience. Chart review forms were created to make history gathering easier before

the first session and to facilitate data entry. Time for each patient's chart review ranged from five to ten minutes. A progress note for each session was dictated using pre-designed forms to generate uniform and rapid documentation. Overall, providers spent approximately 20-30 minutes prior to each session in preparation and about 30 minutes following the session for documentation. Preparation of folders for each patient with packets for each session's educational materials and homework helped limit the amount of provider time required before the meeting.

Running the sessions efficiently was also a skill that improved with time. The first and last sessions were the most difficult because a significant amount of time was spent reading the consent form and completing the two questionnaires. Keeping to a clearly outlined schedule helped ensure that all topics for the day were covered. Overall, there was less time than anticipated for the individual assessments during the break, but many patients used group time to discuss their individual concerns. Some management decisions such as medication changes were made at the end of the session as other members were leaving.

Supplies that were developed over the first few runs of the program included posters for the education room that highlighted key points of the curriculum such as the four key pillars of diabetes treatment; HgbA1c, LDL, and blood pressure goals; and the stages of change model. A large dry-erase board was essential to facilitate group discussion and record

group agenda or questions. A snack and beverage was supplied at each session due to the nearly three-hour duration.

## **RESULTS OF THE INITIAL PILOT STUDY**

Baseline demographic characteristics of the subjects enrolled in the group visit program are shown in Table 3. The mean age of participants was 54 years. Participants were more likely to be African-American than white (75%) and more likely to be married than not (61%). Very few subjects were without insurance (2 out of 32). Level of education was fairly high with over 60% of the subjects having attended some college. Three subjects (11%) did not complete high school. The majority had never attended a diabetes education program before.

Clinical characteristics at baseline are shown in Table 4. Overall, the mean HgbA1c was 8.05% (SD 1.8) slightly higher than the average for our overall clinic population, which is 7.9% (SD 1.3). Average Body Mass Index (BMI) was 33.2 kg/m<sup>2</sup>. Three-quarters of the subjects used some type of medication for management of their diabetes, and nearly half had evidence of at least one micro-vascular complication of diabetes (neuropathy, retinopathy, or nephropathy). Based on chart review of primary care visits and hospitalization reports, 72% of the subjects had hypertension, 63% had hypercholesterolemia, and 19% had known coronary artery disease.

Of the 32 subjects who attended at least one session, only the 24 subjects who attended three of the four sessions were included in the comparison of the pre- and post-intervention outcomes. Several subjects had incomplete data, missing either clinical measures such as blood pressure and weight due to late arrival at the session or incomplete surveys. Of the 12 subjects enrolled in the first cohort, only seven returned completed six-month survey results. Eight had six-month HgbA1c values drawn, and 10 had blood pressure values documented in the clinic record at six months.

Results of the pilot study are shown in Table 5. HgbA1c, weight, BMI, and blood pressure all showed small improvements. Attitudes about diabetes and self-efficacy (as measured by the Diabetes Empowerment Survey overall score) demonstrated improvement at 8-weeks, but a return to baseline levels at 6-months. This finding was evident in all three of the subscales as well. Quality of life (as measured by the SF-12® survey) showed minimal improvement after the intervention.

## **DISCUSSION**

This study demonstrated the feasibility of provider-run group visit program for diabetes education and management in a university-based, primary care clinic. Overall, there were trends towards improved outcomes in clinical areas such as HgbA1c, BMI, and blood pressure control. As found with other short-term interventions, our program improved attitudes

about diabetes, self-efficacy, and quality of life after the eight-week intervention, but it did not show lasting benefits in these areas at six months.

This feasibility study identified important problem areas when implementing this type of program in a real-world clinic setting. We attempted to create and implement this program with limited resources and support staff; somewhat similar to what most primary care clinics would be able to dedicate to such a program. Because of these limited resources, implementation was challenging with the most difficult area being patient recruitment and enrollment. We found that of the 84 inquiries made about the program, only 32 (38%) patients actually attended a session. This represents less than 15% of our clinic's total diabetic population. Maintaining attendance was also difficult with only one-third of subjects attending all four sessions. This low level of interest in diabetes education and management is not surprising. One survey in Philadelphia found that only 22% of subjects with diabetes had ever attended a diabetes education program and found that physician recommendation, female gender, insulin use and higher degree of obesity were important predictors of attendance.[40] Future strategies must develop ways to increase the interest in diabetes education programs and in reducing barriers to attendance. Our program will need to increase exposure of patients to the idea of the diabetes program and to strengthen the primary care physician's role in recommending the program. Greater

incentives and systems to promote attendance may be helpful. Increased group size and more consistent attendance will improve the cost-benefit ratio for the clinic as a whole—making the clinician time devoted to the group sessions worthwhile.

Another challenging aspect of implementation was designing and running the group sessions themselves. We struggled to design each session with the right balance of information, hands-on skills, and group discussion. It was always a challenge to keep each group session well organized and with efficient flow so that all the educational topics were covered and so that individuals could participate freely in group discussion. With time, this skill improved for both group leaders. Future research should identify which aspects of the curriculum are the most effective. Qualitative feedback from group participants may contribute useful information as well.

This pilot study has several limitations. The subjects were not randomized, and there was no control population. As this was a feasibility study, we needed to recruit enough patients in order to run several group sessions. The patients were likely to be a highly motivated group as they were either self-selected or identified by their primary care physician. Involvement was voluntary, and analysis included only those subjects who agreed to participate. The effects of this program cannot be generalized to all patients with diabetes. To truly evaluate the

effectiveness of this intervention, a randomized controlled trial will be needed to eliminate the bias of selection and other confounding factors.

Because this study was conducted in a real-world clinical setting, most of the data collection was obtained from routine clinical care, and not research-driven protocols. This fact limited the completeness and precision of the values collected. For example, clinical data such as blood pressure levels were obtained from chart review of routine primary care visits. No attempt was made to standardize the way that our clinic staff measured blood pressure. Similarly, HgbA1c at six-month follow-up was identified through chart review. Only a disappointing two-thirds of patients had a follow-up value measured between five and seven months after involvement in the program.

Another potential limitation is the variation between the two providers leading the group sessions. Differences in experience, teaching style, and personality may have had dissimilar effects on patients. The curriculum outline and materials used were standardized to limit this variation as much as possible.

The greatest limitation of this intervention is its short duration. Patients did demonstrate changes in attitude and self-efficacy on completion of the eight-week intervention; but it is maintaining these improvements over time that may have the greatest health impact. Group visit interventions with longer duration (at least six months) have often demonstrated more improvement in glycemic control.[29, 31, 33]



A short-term group visit program in a primary care clinic appears feasible, though patient recruitment and attendance need to be improved to maximize cost-effectiveness. Developing an even more innovative model of care is the next step, involving group visits for routine diabetes management and education instead of individual, primary care visits. This has been done in a few selected settings, most notably two large HMO studies and in a specialty-run diabetes clinic in Italy.[31, 32, 34]

Determining whether primary care providers in a non-specialty based clinic can apply this model; whether it will be efficient and cost-effective; and whether it will improve health outcomes needs to be studied.

Providing more efficient and effective primary care strategies for the growing diabetic population is an essential undertaking for our healthcare system. A group visit program for management of diabetes in primary care may meet this challenge.

**Table 1—Curative Factors of Group Therapy[12]**

<b>Curative Factor</b>	<b>Clinical Examples</b>
Interpersonal Learning	<i>Patients learn from each others experiences with diabetes</i>
Catharsis	<i>Sharing the emotions associated with diabetes such as venting anger and sharing fears</i>
Group Cohesiveness	<i>Sense of belonging to the group helps to promote self-esteem and decrease isolation</i>
Insight	<i>Listening to others with diabetes can help patients to understand why they feel or act the way that they do.</i>
Development of Socializing Technique	<i>Getting feedback from others helps to motivate change</i>
Existential Factors	<i>Membership in the group may help to generate improved outlook on life</i>
Universality	<i>Realizing that they are not alone and that other people struggle with the same problems with diabetes</i>
Instillation of hope	<i>Learning from others who have been more successful with their diabetes</i>
Altruism	<i>Feeling that the members of the group are helping one another can be empowering</i>
Corrective recapitulation of family of origin	<i>Group may provide a more positive outlook on family relationships</i>
Imparting information	<i>Sharing of information and learning from each others problem-solving attempts</i>
Imitative behavior	<i>Modeling new behaviors after others in the group who have been more successful</i>

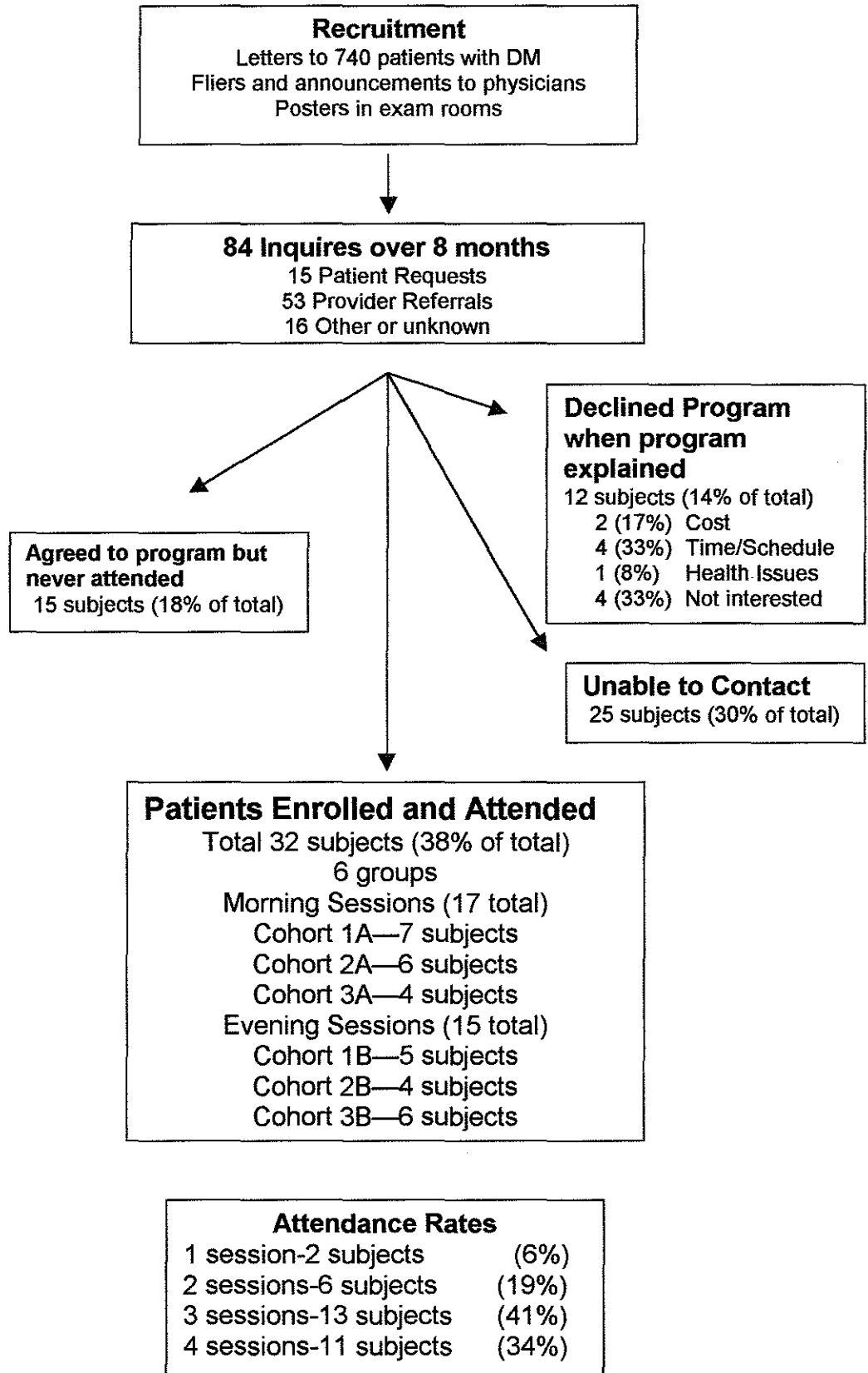
**Table 2 – Review of Randomized Controlled Trials Using A Group Visit Model for Diabetes**

Study	Design	Setting	Intervention description	Population	Group size	Frequency of sessions Duration of Follow-up	Outcomes
Sadur et al.[31]  Diabetes Care 1999	Randomized controlled trial	Large HMO  US	Multi-disciplinary (RN/CDE/Psych/RD) team-led group sessions	Poorly controlled Type II DM (no A1c or >8.5)  97 Intervention 88 Control	10-18 patients	Monthly for six months with RN phone follow-up  Six month to one year follow-up	HgbA1c decreased by 1.3% vs. 0.02% (p<0.0001)  Decreased utilization and increased self- efficacy
Wagner et al[32]  Diabetes Care 2001	Randomized controlled trial  (Randomized by clinic site)	Large HMO  US	Multi-disciplinary team with primary care MD, RN, pharmacist, SW  Seen by MD—then had group education, social support and self- management  Group led by RN/SW "Mini-clinic" model as in Britain	Type II DM  278 Intervention 479 Control  35% invited never attended	6-10 patients	Every three to six months	No difference in A1c, but did show a trend for decreased A1c with increased attendance  Increased preventive services, satisfaction with DM care Increased office visits, but decreased ER visits
Trento et al[34]  Diabetes Care 2001	Randomized controlled trial	General Medicine Clinic with diabetes focus  Italy	Routine group visit with MD vs. individual consultations  1 hour group sessions run by 1-2 physicians and an educationist  Patients seen one-on-one by MD if individual attention needed	Type II DM  56 Intervention 56 Control	9-10 patients	Every three months (Four sessions per year)  Two year follow-up	A1c remained stable in group vs. worsened in individual visits (p=0.0002)  Increased knowledge, Quality of Life, and behaviors Physicians spent less time, patient had more MD time
Rickheim et al[33]  Diabetes Care 2002	Randomized Controlled Trial	Minnesota	Group vs. Individual education sessions with an evidenced based curriculum  Led by RN and RD	Type II DM  87 Intervention 83 Control	4-8 patients	Four sequential sessions over six months  Total of five to seven hours  Six month follow-up	Overall A1c went from 8.5% to 6.5% after 6 months  A1c decreased by 2.5% vs. 1.7% in group vs. control subjects (p=0.05)  No difference in knowledge, behaviors, Quality of life, or attitude (both effective)
Raz et al[27]  Diabetes Care 1988	Randomized Controlled Trial  Stratified based on level of control	Diabetes clinic  Israel	Group diabetes clinic held every 4 months vs. individual sessions only every 2 months  Led by MD/RN/RD/PT	51 patients  Volunteer patients only	Unknown	Three weekly lessons every four months  12 month follow-up	Decreased A1c by 1.5-2% after 12months (p<0.05)  No change in knowledge or weight

**Table 2 (continued)**

Study	Design	Setting	Intervention description	Population	Group size	Frequency/Duration	Outcomes
Ridgeway, et al.[29]  Southern Medical Journal 1999	Randomized Controlled Trial  Used waiting list subjects as control patients	General Medicine Clinic	Led by RN/RD  Monthly group sessions with emphasis on behavior change and life skills  Physician involved on periphery—supportive	Type II DM patients  28 Intervention 28 Control  30% drop out rate	14 patients	Monthly sessions for six month, one follow-up session at 12 months  12 month follow-up  Cost \$195	A1c levels decreased by 2.07% in the intervention group compared to 1.08% in the controls (p=0.0034)  LDL and cholesterol dropped as well at six months in the intervention group
Anderson et al[28]  Diabetes Care 1995	Randomized Controlled Trial  Used waiting list subjects as control	Community patients  University of Michigan	Group education sessions with focus on empowerment for self care  Presentations, worksheets  Guest/family involvement encouraged	64 patients (46 random, 18 not randomly assigned)	Unknown	Six two-hour weekly sessions  12 week follow-up	HgbA1c improved from 11.75% to 11.02% in intervention group compared to 10.82% to 10.78% in the control group (p=0.05)  Improved self-efficacy for goal setting, managing stress, obtaining support, and making decisions
Gaede et al [30]  Diabetic Medicine 2001	Randomized controlled trial	Diabetes Center  Denmark  Steno Type 2 Study	Multi-factorial intervention with both intensive group education and pharmacological therapy  Run by a diabetes team with physician, dietician and nurse	Type II DM age 45-65  160 patients	Unknown	Three individual sessions and two large group sessions with 20 patients/spouses  Smoking cessation group sessions with 14 patients	Improved A1c from 8.4% to 7.6% in the intervention group** compared to a 0.2% increase in the control group (p<.0.000001)  **Likely due to other aspects of intervention such as medication management  No change in lifestyle measures such as exercise or smoking, minimal change in dietary measures

**Figure 1—Recruitment of Subjects**



**Table 3—Demographics of Study Population**

<b>Characteristic (N=32)</b>	<b>Mean (SD) or % (N)</b>	<b>Range</b>
Age	54.2 (11.2)	31-75
Year of Diagnosis	1995	1982-2002
Marital status		
Married	61% (19)	
Widowed	3% (1)	
Single	23% (7)	
Divorced	13% (4)	
Unknown	3% (1)	
Race		
Black	75% (24)	
White	25% (8)	
Gender		
Female	50% (16)	
Male	50% (16)	
Insurance type		
Medicaid	3% (1)	
Medicare	16% (5)	
Private	75% (24)	
None	6% (2)	
Education Level		
Some High School	11% (3)	
Completed High School	29% (8)	
Some College	61% (17)	
Ever attended DM education		
Yes	7% (2)	
No	93% (28)	

**Table 4—Baseline Clinical Characteristics**

<b>Characteristic</b>	<b>Mean (SD) or % (N)</b>	<b>Range</b>
HbgA1c (n=31)	8.05 (1.8)	4.7-12.8
Total cholesterol (n=28)	206.9 (44)	132-339
LDL (n=19)	121.1 (26)	80-171
HDL (n=28)	48.6(12)	32-79
Triglycerides(n=19)	159.4(96)	66-511
Body Mass Index (n=32)	33.2 (7)	19-52.7
Systolic Blood Pressure (n=31)	143.7 (17.7)	118-180
Diastolic Blood Pressure (n=31)	83.9 (12.5)	54-110
DM Management		
Diet only	22% (7)	
Oral medications	66% (21)	
Insulin + oral meds	6% (2)	
Insulin only	6% (2)	
Microvascular Complications		
Yes	47% (15)	
No	41% (13)	
Unknown	12% (4)	
Hypertension		
Yes	72% (23)	
No	25% (8)	
Unknown	3% (1)	
Coronary Artery Disease		
Yes	19%(6)	
No	47%(15)	
Unknown	34%(11)	
Hypercholesterolemia		
Yes	63%(20)	
No	25%(8)	
Unknown	12%(4)	

**Table 5- Results of the Intervention**

<b>Outcomes</b>	<b>Baseline</b>		<b>8 weeks*</b>		<b>6 month**</b>	
	<i>N</i>	<i>Mean (SD)</i>	<i>N</i>	<i>Mean (SD)</i>	<i>N</i>	<i>Mean (SD)</i>
<b>Clinical Measures</b>						
HgbA1c (%)	31	8.05 (1.8)			8	7.79 (1.4)
Weight (lbs)	32	223 (49)	24	219 (45)		
BMI (kg/m <sup>2</sup> )	28	33.6 (7.2)	23	32.9 (6.1)		
Systolic BP (mmHg)	28	144.5 (18)	22	141.0 (22)	10	138.5 (20)
Diastolic BP (mmHg)	32	83.8 (13)	22	80.4 (12)	10	74 (13)
<b>Self-Efficacy/Attitude (DES)</b>						
Psychosocial attitudes	29	3.82 (0.60)	22	4.32 (0.51)	7	3.73 (0.42)
Readiness to change	28	3.80 (0.53)	22	4.31 (0.50)	7	3.94 (0.31)
Goal-setting	27	3.99 (0.48)	22	4.40 (0.41)	7	3.94 (0.24)
Overall empowerment	27	3.87 (0.47)	22	4.35 (0.44)	7	3.87 (0.28)
<b>Quality of Life (SF-12®)</b>						
Physical Component Score (PCS)	28	41.7 (8.1)	18	42.8 (8.4)	7	41.5 (10.7)
Mental Component Score (MCS)	28	45.3 (10.3)	18	47.6 (8.8)	7	46.5 (8.9)

\*For eight-week clinical follow-up, subjects who attended at least three sessions but missed the last session were included with values from the 3<sup>rd</sup> session (six weeks).

\*\*HgbA1c, SBP, and DBP measures were included from five to seven months after the intervention.



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